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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/142,557	09/11/1998	LINDA MAY PILARSKI	P-1459(O)	2357

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PILLSBURY WINTHROP
INTELLECTUAL PROPERTY GROUP
11682 EL CAMINO REAL, SUITE 200
SAN DIEGO, CA 92130

EXAMINER	
MAIER, LEIGH C	

ART UNIT	PAPER NUMBER
1623	

DATE MAILED: 07/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/142,557	PILARSKI, LINDA MAY	
	Examiner	Art Unit	
	Leigh C. Maier	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 April 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *171-197,201 and 203-206* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *195-197 and 205* is/are allowed.

6)☒ Claim(s) *171-194, 201, 203, 204, and 206* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 27, 2004 has been entered.

Any objection or rejection not expressly repeated has been withdrawn. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 102

Claims 171-174, 176, 177, 188-191, 193, 194, and 204 are rejected under 35 U.S.C. 102(e) as being anticipated by TURLEY et al (US 5,767,106).

TURLEY discloses the administration of 15 mg/kg of sodium hyaluronate (mw = 300kD) to a subject having had an induced MI. See experiment 4. Although the reference is silent with regard to the release of cells, as recited, the steps of the methods are accomplished, and the claims are thereby anticipated.

Claims 171, 177, 181, 186, 188, 194, 203, 204, and 206 are rejected under 35 U.S.C. 102(e) as being anticipated by LUSSOW et al (US 6,013,641).

LUSSOW discloses the administration of 1.5 mg/kg of HA having a molecular weight less than 750 kD in conjunction with a heart transplant. See example 2.

Claim Rejections - 35 USC § 103

Claims 171-174, 176, 177, 181-191, 193, 194, and 204 are rejected under 35 U.S.C. 103(a) as being unpatentable over TURLEY et al (US 5,767,106).

TURLEY teaches as set forth above. The reference further teaches that effective doses range from 1-10 mg/kg to about 15-20 mg/kg. See col 2, lines 36-41. The reference does not exemplify the dosage regimen set forth in claims 181-187.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to administer HA in the recited dosage amounts. The artisan would be motivated to use these dosages because TURLEY had taught that these amounts were useful for the treatments of ischemic conditions. In the absence of unexpected results, it would be within the scope of the practitioner to optimize the dosages and dosing schedule in accordance with the needs of the patient. Although the reference may not recognize that the underlying mechanism of the administered HA is the release of H/D cells, the practitioner would be expected to optimize dosages/scheduling based on the patient's symptomology, which should track with said mechanism.

Claims 171-173, 175-183, 185-190, 192-194, 203, 204, and 206 are rejected under 35 U.S.C. 103(a) as being unpatentable over LUSSOW et al (US 6,013,641).

LUSSOW teaches as set forth above. The reference further teaches the use of HA up to about 30 kD has utility in the disclosed invention. See col 2, lines 58-67. The reference further teaches dosages of about 1-25 mg/kg as needed, depending on patient's health. See col 3, lines 38-48. The reference further teaches the administration to patients receiving tissue transplants of a variety of tissues, including stem cells. See paragraph bridging col 3-4. The reference further teaches the use of pharmaceutically acceptable salts. See col 6, lines 13-17. The reference does not exemplify the use of HA having mw of greater than 25 kD or the specific dosages and dosing regimen recite in the claims.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to administer HA, optionally in the form of a salt, having mw of between 25 kD and 100 kD in the recited dosage amounts. The artisan would be motivated to use these dosages because LUSSOW had taught that these amounts were useful for immunosuppression necessary for tissue transplantation. In the absence of unexpected results, it would be within the scope of the practitioner to optimize the dosages and dosing schedule in accordance with the needs of the patient. Although the reference may not recognize that the underlying mechanism of the administered HA is the release of H/D cells, the practitioner would be expected to optimize dosages/scheduling based on the patient's symptomology, which should track with said mechanism.

Claim 201 is rejected under 35 U.S.C. 103(a) as being unpatentable over FALK et al (US 5,914,314).

FALK teaches the use of HA having mw of less than 750 kD for a variety of uses. See abstract and col 19, lines 53-57. One of the uses is as a perfusate for tissue to be transplanted. See table in col 20, entry 18. The reference does not exemplify this utility.

It would be obvious to one having ordinary skill in the art at the time the invention was made to infuse an ex vivo organ to be transplanted. The reference teaches that infusion enhances oxygenation. The reference is silent with regard to cell mobilization. However, it would be within the scope of the artisan to optimize the amount necessary for the desired use of enhancing oxygenation with a reasonable expectation of success. In the absence of unexpected results, this optimization would also be expected to accomplish the mobilization of cells.

Allowable Subject Matter

Claims 195-197 and 205 are allowed.

The following is a statement of reasons for the indication of allowable subject matter: LUSSOW teaches as set forth above. The reference does not teach or reasonably suggest a method comprising administration of HA to an organ/tissue *donor* in conjunction with an organ/tissue transplant.

Examiner's hours, phone & fax numbers

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leigh Maier whose telephone number is (571) 272-0656. The examiner can normally be reached on Tuesday, Wednesday, and Friday 7:00 to 3:30 (ET).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson (571) 272-0661, may be contacted. The fax number for Group 1600, Art Unit 1623 is (703) 872-9306.

Visit the U.S. PTO's site on the World Wide Web at http://**www.uspto.gov**. This site contains lots of valuable information including the latest PTO fees, downloadable forms, basic search capabilities and much more.

Leigh C. Maier
Patent Examiner
July 12, 2004